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ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,304	TROTTA, CHRISTOPHER R	
	Examiner	Art Unit	
	SUE LIU	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-66 and 83-89* is/are pending in the application.

4a) Of the above claim(s) *44,47,49-61,65 and 66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42,43,45,46,48,62-64 and 83-89* is/are rejected.

7)☒ Claim(s) *48 and 63* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/17/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

1. Claims 1-41, 67-82 have been canceled as filed on 8/17/09.

Claims 83-89 have been added as filed on 8/17/09.

Claims 42-66 and 83-89 are currently pending.

Claims 44, 47, 49-61, 65 and 66 have been withdrawn.

Claims 42, 43, 45, 46, 48, 62-64 and 83-89 are being examined in this application.

Election/Restrictions

2. Applicant's election of Group 1 (claims 42-66) in the reply filed on 12/22/08 is as previously acknowledged. The newly added claims 83-89 are grouped with the elected Group 1 invention.

3. Applicant's election without traverse of the following species:

A.) reduces fungal tRNA splicing endonuclease activity;

B.) intact cells;

C.) a reporter gene assay;

in the reply filed on 12/22/08 is as previously acknowledged. Applicants also state "claims 42, 43, 45, 46, 48, 62, 63 and 64 read on the elected species." Accordingly, Claims 44, 47, 49-61, 65 and 66 are withdrawn due to non-elected species.

Priority

4. This application is filed under 35 U.S.C 371 of PCT/US04/09574 (filed on 03/26/2004), which claims priority to US provisional applications 60/458,090 (filed on 3/27/2003).

Information Disclosure Statement

5. The IDS filed on 8/17/09 has been considered. See the attached PTO 1449 forms.

Specification

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. MPEP 608.01.

Claim Objection(s) / Rejection(s) Withdrawn

7. Upon further consideration and in light of applicant's arguments, the following claim rejection(s) as set forth in the previous office action is(are) withdrawn:

A.) Claims 42, 43, 45, 46, 48 and 62-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claim Objection(s) / Rejection(s) Maintained

Claim Objections

8. Claim 48 is objected to because the said claim depends on a non-elected claim (Claim 47) that is drawn to a non-elected invention.

Claim 63 is objected to because the said claim depends on a non-elected claim (Claims 53 and 59) that is drawn to a non-elected invention.

Appropriate correction is requested.

Discussion and Answer to Argument

9. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants requested the claim objection be held in abeyance. Applicants have not provided any specific traversal over the above claim objection. Thus, the above objection is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Tocchini-Valentini and Gontarek

11. Claims 42, 43, 45, 46, 48 and 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Tocchini-Valentini** et al (WO 01/92463; 12/6/2001; Cited in IDS), in view of **Gontarek** (WO 00/67580; 11/16/2000; cited in IDS).

The instant claims recite "A method for identifying a compound that modulates fungal tRNA splicing endonuclease activity, the method comprising:

(a) contacting a compound or a member of a library of compounds with a fungal tRNA splicing endonuclease and a substrate for tRNA splicing endonuclease comprising a nucleic acid, wherein the nucleic acid comprises a tRNA intron within a bulge-helix-bulge structure or a mature domain of a precursor tRNA; and

(b) detecting the amount of substrate cleaved, wherein a compound that modulates fungal tRNA splicing endonuclease activity is identified if the amount of substrate cleaved in the presence of a compound is altered relative to the amount of substrate cleaved in the absence of the compound or in the presence of a negative control."

Tocchini-Valentini et al., throughout the publication, teaches methods of monitoring tRNA splicing endoclease activity on various target molecules (e.g. Abstract). The reference teaches contacting a substrate for tRNA splicing endonuclease with a tRNA splicing endonuclease (e.g. pp.6+; Figures), which read on the tRNA splicing endonuclease and the substrate of step (a) **clm 42**. The reference also teaches the substrate contain "bulge-helix-bulge"

structure (e.g. pp.6+; Figure 5). The reference also teaches detecting the amount of substrate cleaved (e.g. p.7+; Figures; Claims), which reads on the detecting substrate cleaved of step (b) of **clm 42**. The reference also teaches the tRNA splicing endonuclease is from yeast (e.g. p.16, [0054]; p.8), which reads on the "fungal tRNA splicing endonuclease" of **clm 42**.

The reference also teaches the substrate with the bulge-helix-bulge structure is part of a reporter gene (e.g. GFP) (e.g. Figure 5; p.4; p.25), which reads on the reporter gene of **clms 45** and **62**.

The reference also teaches detecting the GFP expression as an indication of the endonuclease activity (e.g. p.25; Figures), which reads on the reporter activity step of **clms 46** and **48**.

The reference also teaches endonuclease from yeast such as S. cerevisiae (e.g. p.16). The reference also teaches using endogenous tRNA splicing endonuclease in in vivo experiments (e.g. p.8).

Tocchini-Valentini et al do not explicitly teach assaying for a compound that can reduce (or inhibitor) RNA splicing as recited in **clms 42**, **43**, **46** and **48**. The reference also does not explicitly teach using a fungal cell such as a yeast cell as recited in **clm 46**, **63** and **64**.

However, **Gontarek**, throughout the publication, teaches methods or assays for screening for compound that modulate splicing reactions. (e.g. Abstract). The reference teaches contacting a compound to a splicing reaction to "inhibit" the splicing reaction (e.g. Claim 1; p.2). The reference also teaches screening for compounds that modulate splicing reactions using in vivo splicing reactions (i.e. in intact cells) (e.g. Abstract). The reference also teaches the method of screening compounds can be used to identify inhibitors of "splicing polypeptides" so that

"fungistatic and/or fungicidal" compounds can be identified (e.g. p.23, lines 3+) or to advance understanding of RNA splicing (e.g. p.1). The reference also teaches using yeast cells (such as S. cerevisiae) as host cells (e.g. p.18, lines 28+).

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to screening for inhibitors of RNA splicing such as tRNA splicing by contacting cells (comprising splicing reaction components) such as yeast cells with a compound of interest.

A person of ordinary skill in the art would have been motivated at the time of the invention was made to contact cells with compounds of interest to measure the amount of RNA splicing, because Gontarek teaches the need to screen for compounds that are inhibitor of RNA splicing mechanism so that various useful compounds such as fungicidal compounds can be identified or useful compounds for studying RNA splicing (such as tRNA splicing). It would have been obvious to a person of ordinary skill in the art to try various combinations of the known methods of screening for compounds of interested based their abilities to inhibit RNA splicing in cells, methods of detecting RNA splicing using tRNA splicing endonuclease with the appropriate substrate, etc., in an attempt to optimize and/or improve the screening method of detecting RNA splicing inhibitors in cells, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

A person of ordinary skill in the art would have been motivated at the time of the invention was made to use yeast cells as for the screening assay, because Tocchini-Valentini et al and Gontarek teach the need to use yeast cells as the cells would offer endogenous tRNA splicing endonuclease. In addition, because both the cited references teach methods of using

yeast cells and/or other cells for in vivo splicing experiments to assay for RNA splicing, it would have been obvious to one skilled in the art to substitute one type of cells for the other to achieve the predictable result of assaying for RNA splicing in the presence or absence of a compound of interest.

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications since the cited references have demonstrated the success of detecting the amount of tRNA splicing endonuclease activity using appropriate substrate using a reporter gene system in an in vivo system and the success of using an in vivo system to screen for an inhibitor of RNA splicing mechanism.

Discussion and Answer to Argument

12. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants assert "There is no teaching or suggestion in Tocchini-Valentini that tRNA splicing endonuclease may be used as a drug target and to screen for compounds that modulate the activity of fungal tRNA splicing endonuclease." (Reply, pp.14+).

Applicants traversed the above rejection over the combination of the cited references by traversing the Tocchini-Valentini reference alone. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642

F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Further, applicants are also respectfully directed to the Supreme Court decision, which forecloses the argument that a specific teaching, suggestion, or motivation is required in the references to support a finding of obviousness. *KSR, 127 S.Ct. at 1741, 82 USPQ2d at 1396.*

Applicants also argue the Gontarek reference teaches screening for compound thtat modulate fungal pre-mRNA splicing (not tRNA splicing), and thus the cited references cannot be combined because there are "functional differences between mRNA splicing and tRNA splicing" (Reply, pp.15+).

Applicants also assert "one of ordinary skill in the art to substitute one splicing pathway for another" (Reply, p.15, para4). The above rejection over the combination of cited reference does not rely on the reasoning that one can simply substitute one RNA splicing pathway for the other. Applicants are respectfully directed to the above rejection for the reasoning statements to combine the references. The instant claim is drawn to a screening method with the steps of detecting tRNA splicing in the presence of a compound (which the compound can be any compound). The instant claimed screening method is similar to any compound screening method, where compounds are contacted with a reaction/assay mixture (such as a tRNA splicing reaction mixture or cell containing the splicing components). The detailed mechanism of how the splicing actually occurs, in a sense, is irrelevant to the screening assay. That is as long as the components in a reaction/assay (such as a tRNA splicing reaction) are known and the assay system has been demonstrated to produce observable outcome (the spliced tRNA substrate), one of skill in the art

can simply add testing compounds to the assay system and determine the effect of the compound (i.e. production or inhibition of the splicing reaction). Applicants have not provided any evidence to show that adding compounds to tRNA splicing assay to detect the effect of the compounds is highly unpredictable. Although there are differences in mRNA and tRNA splicing, applicants have not demonstrated how the difference would render the screening assay inoperable.

In fact, the state of the art supports the predictability of screening compounds for various RNA processing events. For example, **Rana** et al. (WO 01/25486; 4/12/2001; cited in IDS), throughout the publication teach general methods/assays for identifying RNA binding compounds. The reference teaches by identifying RNA binding compounds, compounds that can inhibit RNA-protein interaction (i.e. inhibit RNA processing events depending on the protein). The reference also teaches the assay or screening methods are applicable to identify compounds involved in various tRNA processes. As pointed out by applicants (Reply, pp.16-17), at least one common mechanism, protein binding to RNA, would be required for both mRNA and tRNA splicing. That is the tRNA endonuclease must bind to the tRNA for the reaction to occur. It would be predictable to screen for compounds that would inhibit such interaction.

Therefore, it would have been obvious to a person of ordinary skill in the art to try various combinations of the known methods of screening for compounds of interested based their abilities to inhibit RNA splicing in cells, methods of detecting RNA splicing using tRNA splicing endonuclease with the appropriate substrate, etc., in an attempt to optimize and/or improve the screening method of detecting RNA splicing inhibitors in cells, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

Applicants also assert "Neither Tocchini-Valentini nor Gontarek provide any indication that a fungal tRNA splicing endonuclease might be a suitable drug target." (Reply, p.17).

However, the instant claims are not drawn to a method that require the compounds to be used as a "drug target." In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "drug target") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regardless whether or not tRNA splicing endonuclease can be a suitable drug target, one of skilled in the art would be motivated to test for compounds that would modulates (or inhibit) the tRNA splicing endonuclease because the identified compounds would at least provide a useful research tool for studying the tRNA splicing mechanism.

New Claim Objection(s) / Rejection(s)

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter Rejection

14. Claims 83-86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is necessitated by applicant's amendments to the claims.

Claims 83-86 have been added (as filed on 8/17/09) to recite a method step of "contacting the compound with an animalia tRNA splicing endonuclease and the substrate", which the substrate is interpreted to mean the same substrate used for the fungal tRNA splicing step in claim 42 (or other preceding claims). However, the instant specification does not provide support for this specific step of using the same substrate for both the animal and fungal tRNA. Applicants pointed to page 91 for support of the newly added claims. However, the cited passage of the instant specification is generic and does not provide support for such a method step.

If Applicant believes this rejection is in error, applicant must disclose where in the specification support for the entire scope of the amendment(s) and/or new claims can be found. As a result, Claims 83-86 represent new matter.

Claim Rejections - 35 USC § 103

Tocchini-Valentini and Others

Claims 42, 43, 45, 46, 48, 62-64 and 87-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Tocchini-Valentini** et al (WO 01/92463; 12/6/2001; Cited in IDS), in view of **Gontarek** (WO 00/67580; 11/16/2000; cited in IDS), and if necessary, in view of **Abelson** et al. (Journal of Biological Chemistry. Vol.273 (21): 12685-12688; 1998; cited in IDS). This rejection is necessitated by applicant's amendments to the claims.

Tocchini-Valentini et al., throughout the publication, teaches methods of monitoring tRNA splicing endoclease activity on various target molecules, as discussed supra.

Gontarek, throughout the publication, teaches methods or assays for screening for compound that modulate splicing reactions, as discussed supra.

The combined teaching of the Tocchinin and Gontarek references as discussed supra are hereby incorporated by reference in its entirety.

The combination of the Tocchinin and Gontarek references does not explicitly teach using the precursor tRNA has a mature domain as recited in **clms 87-89**.

However, **Abelson** et al., throughout the publication, teach tRNA splicing and the substrates for splicing. The reference specifically teaches using pre-tRNA with "a mature domain" (e.g. p.12685, right col.) The reference also teaches the mature domain is important for proper splicing to occur and it is part of the natural recognition mechanism (e.g. p.12685).

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use a pre-tRNA with a mature domain in a tRNA splicing assay.

A person of ordinary skill in the art would have been motivated at the time of the invention to use a pre-tRNA with a mature domain, because Abelson et al. teach the mature domain is naturally occurring and is needed for proper tRNA splicing recognition. In addition, because the cited references teach methods of tRNA splicing using various substrates, it would have been obvious to one skilled in the art to substitute one substrate for the other (one with a mature domain) to achieve the predictable result of properly splicing pre-tRNA for tRNA splicing assays.

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications since the cited references have demonstrated the success of splicing various tRNA substrates.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

'301

16. Claims 42, 43, 45, 46, 48, 62-64 and 83-89 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 55-57, 63-74, 76-82 and 91-95 of copending Application No. 10/551,301 in view of Tocchini-Valentini et al (WO 01/92463; 12/6/2001; Cited in IDS). This rejection is necessitated by applicant's filing of an IDS (filed on 8/17/09) disclosing the '301 patent application.

The '301 application claims a method of identifying a compound that modulates animalia tRNA splicing endonuclease activity using various reagents and/or method steps. (see claim 55 of '301).

The '301 application does not explicitly claim screening for fungal tRNA splicing endonuclease.

However, Tocchini-Valentini et al., throughout the publication, teaches methods of monitoring tRNA splicing endoclease activity on various target molecules in various eukaryotic systems including fungus and Xenopus (e.g. pp.17+). It would have been obvious to one skilled in the art to substitute one type of tRNA splicing endonuclease (animalia) for the other (fungal) to achieve the predictable result of conducting tRNA splicing assay in the presence of a compound.

This is a provisional obviousness-type double patenting rejection.

Conclusion

17. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 8/17/09 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SUE LIU/
Primary Examiner, Art Unit 1639
11/7/09